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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,979	03/25/2004	Qiong Cheng	CL2360USNA	8665

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WILMINGTON, DE 19805

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,979

Applicant(s)

CHENG ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005 & 18 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As asserted in Applicant's letter of 05 May 2005, the Notice Regarding Sequence Compliance of 31 January 2005 was sent in error. See also page 2 of the Office action of 10 February 2005, where this is stated.

Applicant's amendments of 18 May 2005 have obviated the objection to the specification, the outstanding indefiniteness rejection, and the rejections of claim 16 under 35 USC 112, first paragraph regarding transformed multicellular hosts.

Claim 17 (newly amended) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, drawn to plant cells, fails to further limit newly amended claim 16, limited to microbial cells, from which claim 17 depends. Amendment of claim 17 to delete " , and green plants" in lines 2-3; and to insert ---and--- before "algae" in line 2; would obviate this rejection.

Claims 13-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention; regarding vectors, chimeric genes, or transformed hosts comprising the crtZ gene, as stated on pages 3-5 of the last Office action for claims 6 and 13-18.

Claims 6 and 13-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, regarding variants of SEQ ID NO:18, as stated on pages 6-8 of the last Office action.

Claims 13-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, regarding vectors, chimeric genes, or transformed hosts comprising the crtZ gene, as stated on pages 11-14 of the last Office action for claims 6 and 13-18.

Claims 6 and 13-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, regarding variants of SEQ ID NO:18, as stated on pages 14-17 of the last Office action.

Claims 6 and 13-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use

the invention, regarding a biological deposit, as stated on pages 20-21 of the last Office action.

Claims 6 and 13-18 remain free of the prior art, as stated on page 21 of the last Office action.

No claim is allowed.

Applicant's arguments filed 18 May 2005, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejections are improper, given the disclosure of SEQ ID NO:18 which encompasses all of the recited genes, and given the recitation of at least 95% sequence identity thereto, as recited on pages 4 and 30 of the specification. See pages 4-5 of the Response of 18 May 2005, paragraph numbers 5 and 6.

The Examiner acknowledges that page 27 of the specification, lines 33-35, states that SEQ ID NO:18 includes the crtZ gene, as argued on page 6 of the Response of 18 May 2005. However, the Examiner maintains that it is unclear whether vectors or chimeric genes comprising entire SEQ ID NO:18 have been reduced to practice, as stated below. Thus, claims drawn to said vectors, chimeric genes, or host cells transformed therewith remain inadequately described.

Regarding the second written description rejection pertaining to sequence variants, the Examiner maintains that neither excerpted portion of the specification (see page 4 of the Response of 18 May 2005, bottom paragraph) provides an actual description for sequence variants having at least 95% identity to entire SEQ ID NO:18.

Page 4, line 38 of the specification merely describes stringent hybridization conditions and isolated nucleic acid molecules which hybridize to *individual* crt genes, encoding SEQ ID NOS: 2, 4, 6, 8, 10 or 12. No mention of sequence identity is made, and no mention is made of hybridization to an entire crtZ operon or to the entire length of SEQ ID NO:18. Page 30 of the specification, lines 3-16, recites sequences about 95% identical to an *individual* crtZ gene.

Applicant urges that the enablement rejections are improper, given the disclosure on page 27 of the specification, line 33 that SEQ ID NO:18 comprised all of the crtEXYIBZ operon; and given the statement in Example 4, on page 61 of the specification, that the crt gene cluster from Example 3 was used to transform another *Methylomonas* bacterial strain. Applicant further urges that the functional language of the claim precludes inoperative embodiments regarding sequence variants. See pages 5-6 of the Response of 18 May 2005, paragraph numbers 8 and 9.

The Examiner acknowledges Applicant's statement in the specification that SEQ ID NO:18 comprises all genes of the crt gene cluster, including crtZ. However, it remains unclear whether the fragment used in Example 4 comprised the entire SEQ ID NO:18. The specification on page 61, lines 9-10, merely states that "the crtEXYIB genes" were introduced into a heterologous bacterial strain. The specification does not state that the entire portion of the crt gene cluster was used. It appears that bacteria transformed with only the crtEXYIB genes would not produce the desired carotenoids, so that one skilled in the art would not know how to use said transformants.

Applicant is invited to submit a declaration under 37 CFR 1.132 clarifying what genes were actually transferred into the bacterium of Example 4, and what carotenoids if any were produced by the transformant. No commitment is made regarding consideration of such a declaration if submitted with an amendment made after final rejection.

Regarding the functional language of the claims, the Examiner maintains that no sequence variants have actually been evaluated for their ability to encode all of the crt gene products, and to produce the desired carotenoid types. Indeed, the claims read on a multitude of sequence variants in which all of the variability occurs in one or a few crt genes, resulting in gene knockouts. Thus, the claims read on a multitude of inoperative embodiments, and no guidance has been provided in the specification regarding the identification of operable sequence variants or any consensus sequences therein. In addition, no guidance has been provided for how to use transformants comprising less than the full complement of crt genes.

See *Atlas Powder v. DuPont*, 224 USPQ 409, 414 (Fed. Cir. 1984), where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation.

Applicant urges that the deposit rejection is improper, since SEQ ID NO:18, rather than the source bacterial strain, is all that is required. See page 7 of the Response of 18 May 2005, paragraph number 11.

The Examiner maintains that it is unclear whether vectors or chimeric genes comprising entire SEQ ID NO:18, and hosts transformed therewith, have in fact been

obtained. The claims appear to read on fragments of the strain DC260 genome, so that the deposit of the bacterial strain would have been required for their enablement.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 18, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

